



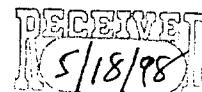
PHARMANEX

A Natural Healthcare Company

Pharmanex, Inc.
625 Cochran Street
Simi Valley, California
93065-1939
805 582 9300
Fax 805 582 9301

0396 '96 JUN 23 P2:13
May 18, 1998

BY FEDERAL EXPRESS



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

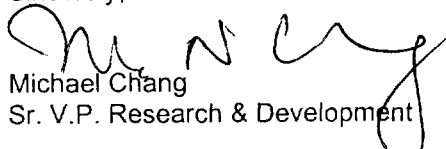
As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Echinacea Plus Goldenseal**, containing Echinacea purpurea root extract (*Echinacea purpurea*) and Goldenseal root extract (*Hydrastis canadensis*), with the following labeling statements:

1. Supports natural resistance.
2. Echinacea plus Goldenseal supports natural resistance by stimulating the body's defense systems, and may be useful during the cold and wet weather seasons.
3. Goldenseal is added to support the health of the body's microbial environment.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

97S-0162

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59146



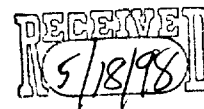
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Product identified as **Echinacea**, containing Echinacea purpurea root (*Echinacea purpurea*), with the following labeling statements:

1. Stimulates body's natural defenses.
2. Since Echinacea has been shown in scientific studies to stimulate the body's natural defense systems, it may be useful during the cold and wet weather seasons.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



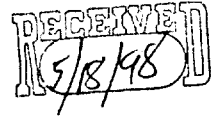
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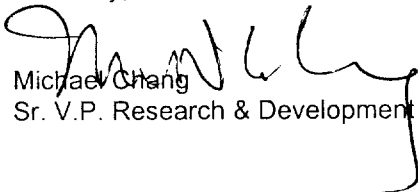
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Product identified as **Ginger**, containing Ginger root extract (*Zingiber officinale*), with the following labeling statements:

1. Helps soothe the stomach.
2. Cultivated for thousands of years, Ginger has been shown to help stimulate digestion and may be helpful for a bloated feeling.
3. Ginger also helps soothe the stomach, and promote stomach comfort when traveling.
4. Ginger may be taken a few days prior to travel or each day during the trip to help maintain stomach equilibrium.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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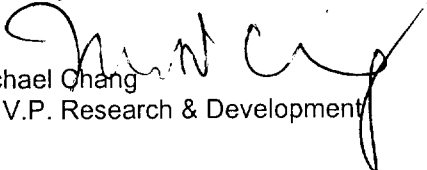
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Product identified as **Odorless Garlic**, containing Garlic clove powder (*Allium sativum*), with the following labeling statements:

1. Supports cardiovascular health.
2. Our garlic is specially processed to retain many of the natural compounds suggested to support cardiovascular health.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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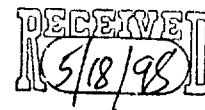
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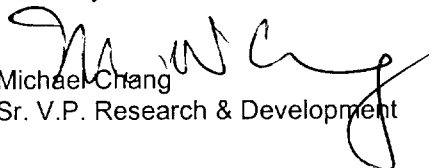
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Product identified as **Feverfew**, containing Feverfew leaves and flowers extract (*Tanacetum parthenium*), with the following labeling statements:

1. Promotes cerebral blood vessel tone.
2. Feverfew may help maintain cerebral blood vessel tone through its ability to inhibit the release of serotonin, which can cause constriction of blood vessels in the head.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


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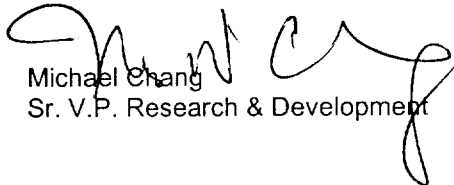
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Product identified as **Dong Quai**, containing Dong quai root extract (*Angelica sinensis*), with the following labeling statements:

1. Women's health formula.
2. Dong quai provides dietary support for the health of the reproductive system throughout the phases of a woman's life.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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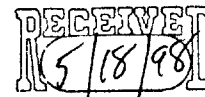
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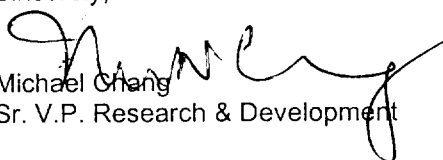
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Product identified as **Cordyceps**, containing *Cordyceps sinensis* mushroom mycelia, with the following labeling statements:

1. Enhances stamina.
2. Promotes healthy lung function.
3. Scientific research suggests Cordyceps may enhance stamina through its ability to promote healthy lung function.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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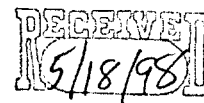
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Dear Sir or Madam:

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Product identified as **Co Q10**, containing Coenzyme Q10 (*Ubiquinone*) and vitamin E (from mixed tocopherols), with the following labeling statements:

1. Promotes healthy heart function.
2. Many organs, especially the heart, require appropriate amounts of Co Q10 to function at optimal levels.
3. Co Q10 helps produce energy at the cellular level to nutritionally support the body's most active muscle—the heart.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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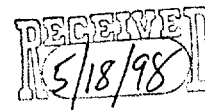
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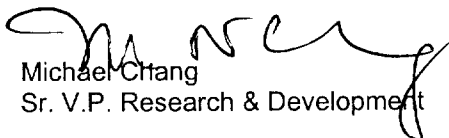
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Product identified as **Cayenne**, containing Cayenne pepper fruit (*Capsicum annuum*), with the following labeling statements:

1. Supports healthy digestion.
2. The capsaicin content of cayenne may help aid digestion and the breakdown of foods by stimulating the release of digestive enzymes.
3. Although hot to the taste, cayenne helps dissipate body heat.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



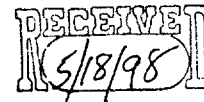
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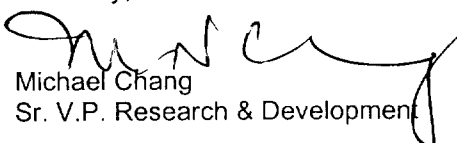
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Product identified as **Bilberry**, containing Bilberry fruit extract (*Vaccinium myrtillus*), with the following labeling statements:

1. Promotes eye health.
2. Enhances circulation.
3. Bilberry may result in positive health benefits for the eyes by strengthening capillaries and promoting healthy circulation.
4. Bilberry may also help support normal visual adaptation to both darkness and light.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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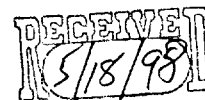
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Product identified as **Astragalus**, containing Astragalus root extract (*Astragalus membranaceus*), with the following labeling statements:

1. Adaptogen for stress.
2. Enhances body's defense systems.
3. It has the properties of an adaptogen, which means it enhances the body's natural defense mechanisms to better handle the stresses of changing environments and demanding lifestyles.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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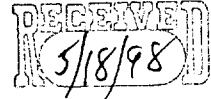
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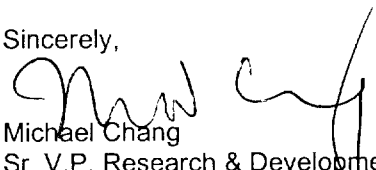
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Product identified as **Saw Palmetto**, containing Saw palmetto berries extract (*Serenoa repens*), with the following labeling statements:

1. Promotes prostate health.
2. Use of Saw palmetto has been associated with healthy prostate function.
3. Our extract provides the naturally occurring compounds in Saw palmetto that support the health of prostate tissue and normal urinary function.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
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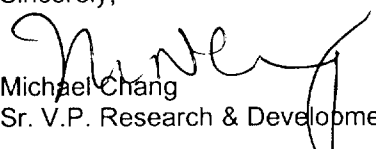
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Product identified as **Reishi**, containing Reishi mushroom extract (*Ganoderma lucidum*), with the following labeling statements:

1. Naturally calms nerves.
2. This well researched mushroom may help calm nerves.
3. Reishi also helps augment the body's natural defense system, and ability to handle life's stressful changes.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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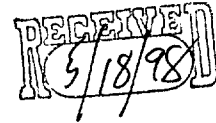
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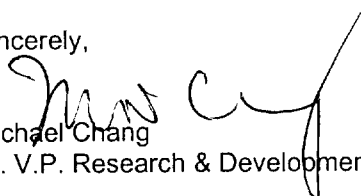
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Product identified as **Panax Ginseng**, containing Ginseng, Panax root extract (*Panax ginseng* C.A. Meyer), with the following labeling statements:

1. Promotes healthy energy levels.
2. Modern research supports Panax ginseng's use in promoting healthy energy levels.
3. By enhancing more efficient use of glycogen (fuel for muscle), Panax ginseng may help increase physical and mental work capacity.

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Sincerely,


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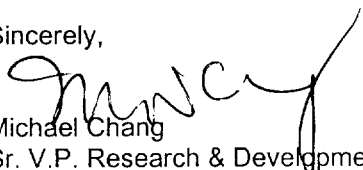
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Product identified as **Milk Thistle**, containing Milk thistle seed extract (*Silybum marianum*), with the following labeling statements:

1. Supports liver health.
2. Helps counter effects of toxins.
3. Milk thistle naturally contains the antioxidant silymarin, which helps support the liver—the major detoxifying organ in the body.
4. It (Milk thistle) helps to counter the effects of pollutants, alcohol, pesticides and other toxins from our environment, diet and lifestyles.
5. Key constituents in Milk thistle may enhance the activity of liver enzymes—supporting liver detoxification reactions and liver cell health.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


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Dear Sir or Madam:

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Product identified as **Kava Kava**, containing Kava kava root extract (*Piper methysticum*), with the following labeling statements:

1. Promotes relaxation of body and mind.
2. Kava kava provides dietary support to naturally relax the mind and body (including the muscles), and help you rest more easily.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

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Product identified as **Hawthorn**, containing Hawthorn flowers and leaves extract (*Crataegus oxyacantha*), with the following labeling statements:

1. Maintains healthy heart function.
2. Scientific studies with Hawthorn extract suggest that it may support healthy heart function by enhancing cardio blood flow.
3. A healthy heart is essential for overall well-being and vitality.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

Michael Chang
Sr. V.P. Research & Development

59146



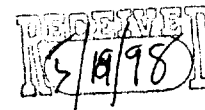
PHARMANEX

A Natural Healthcare Company

Pharmanex, Inc.
625 Cochran Street
Simi Valley, California
93065-1939
805 582.9300
Fax 805 582 9301

May 18, 1998

BY FEDERAL EXPRESS



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:


As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Grape Seed**, containing Grape seed extract (*Vitis vivifera*), with the following labeling statements:

1. Safeguards body's cells.
2. Promotes vein circulation in the legs.
3. Grape seed offers potent antioxidant support through its significant levels of water-soluble proanthocyanidins.
4. These substances (proanthocyanidins) may enter the bloodstream more easily and help to safeguard the body's cells from the effects of free radicals, which may damage cells.
5. Grape seed may be helpful for venous (vein) circulation in the legs.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



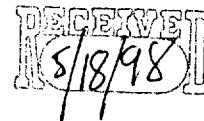
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U.S. Food and Drug Administration
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Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Green Tea**, containing Green tea extract (*Camellia sinensis*), with the following labeling statements:

1. Protects cells and DNA.
2. Green tea has been extensively studied for its antioxidant properties.
3. Green tea may help prevent free radical cell damage from pollution, toxins, smoke and stress common in today's environment.
4. As an antioxidant, green tea extract has been shown to protect cells and DNA from breakdown by free radicals.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Cheng
Sr. V.P. Research & Development

59146



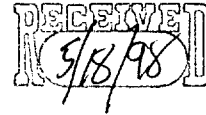
PHARMANEX

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625 Cochran Street
Simi Valley, California
93065-1939
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Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

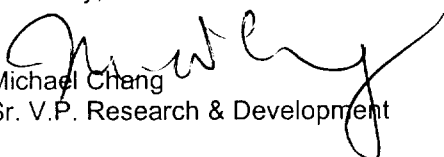
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Product identified as **Grape Seed**, containing Grape seed extract (*Vitis vivifera*), with the following labeling statements:

1. Safeguards body's cells.
2. Promotes vein circulation in the legs.
3. Grape seed offers potent antioxidant support through its significant levels of water-soluble proanthocyanidins.
4. These substances (proanthocyanidins) may enter the bloodstream more easily and help to safeguard the body's cells from the effects of free radicals, which may damage cells.
5. Grape seed may be helpful for venous (vein) circulation in the legs.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



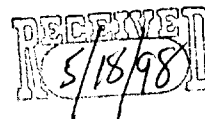
PHARMANEX

A Natural Healthcare Company

Pharmanex, Inc.
625 Cochran Street
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93065-1939
805 582 9300
Fax 805 582 9301

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

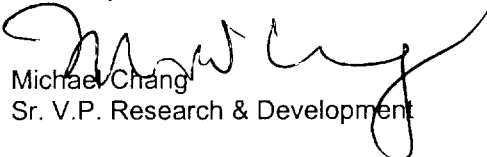
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Product identified as **Ginkgo**, containing Ginkgo leaf extract (*Ginkgo biloba*), with the following labeling statements:

1. Promotes circulation to the brain and body.
2. May help memory.
3. As one of the best researched botanicals in the world, Ginkgo has been shown to enhance circulation to the brain, arms and legs.
4. By promoting healthy blood and oxygen flow to the brain, Ginkgo may help memory.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



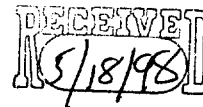
PHARMANEX

A Natural Healthcare Company

15946

Pharmanex, Inc.
625 Cochran Street
Simi Valley, California
93065-1939
805.582.9300
Fax 805.582.9301

May 18, 1998



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Office of Special Nutritionals (HFS-450)
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U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

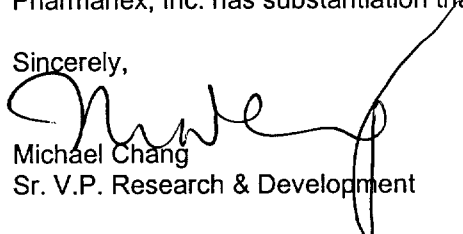
As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Vitex**, containing Vitex fruit extract (*Vitex agnus castus*), with the following labeling statements:

1. Support women's reproductive health.
2. Supported by extensive scientific research in Europe, Vitex could affect the healthy balance of the pituitary gland's production of key hormones (estrogen and progesterone) associated with a woman's monthly cycle.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



PHARMANEX

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Office of Special Nutritionals (HFS-450)
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U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Valerian**, containing Valerian root extract (*Valeriana officinalis*), with the following labeling statements:

1. Promotes restful sleep.
2. May improve sleep quality.
3. Valerian promotes restful sleep and may improve sleep quality, especially in pressured and overworked individuals.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,



Michael Chang
Sr. V.P. Research & Development

59146



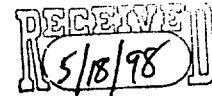
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Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

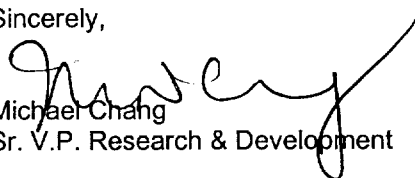
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Product identified as **Uva Ursi**, containing Uva ursi leaf extract (*Arctostaphylos uva-ursi*), with the following labeling statements:

1. Promotes urinary tract health.
2. Uva ursi helps support urinary tract health through its cleansing properties if the urine is alkaline.
3. It also promotes bladder and kidney health.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



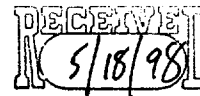
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200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **St. John's wort**, containing St. John's wort flowering tops and leaves (*Hypericum perforatum*), with the following labeling statements:

1. Healthy emotional balance support.
2. St. John's wort may promote a healthy emotional balance, positive moods, and healthy sleep patterns.
3. Research suggests St. John's wort promotes a positive mental outlook by modulating the healthy functioning of the brain's neurotransmitters.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



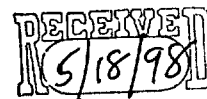
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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Siberian Ginseng**, containing Ginseng, Siberian root extract (*Eleutherococcus senticosus* Max), with the following labeling statements:

1. Physical and mental stress support.
2. As an adaptogen, Siberian ginseng may enhance the body's ability to handle the physical and mental demands of modern lifestyles.
3. Research suggests it may improve the efficiency of oxygen and energy use during periods of stress.
4. Taken as directed, it provides nutritional support for people experiencing stress on a regular basis.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

59146



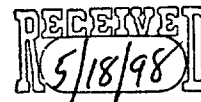
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93065-1939
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Office of Special Nutritionals (HFS-450)
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U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

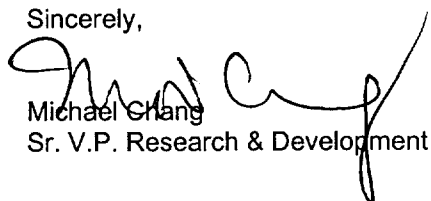
As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Schisandra**, containing Schisandra berries extract (*Schisandra chinensis*), with the following labeling statements:

1. Promotes alertness.
2. May help quicken reflexes.
3. Schisandra may help stimulate the nervous system as it relates to alertness and quick reflexes.
4. Its key constituents, the bioactive lignans, appear to have liver-protective benefits.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

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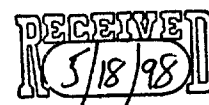
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RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Evening Primrose Oil**, containing Evening primrose seed oil extract (*Oenothera biennis*), with the following labeling statements:

1. Evening primrose oil is a rich source of essential free fatty acids, especially gamma-linolenic acid (GLA)—not found in commonly consumed foods, yet required by our bodies for many vital functions, such as healthy skin and the structure of all cell membranes in the body.
2. Evening primrose also provides nutritional support for women with breast tenderness that may occur during monthly cycles.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

see docket 97S-0163 also

59146



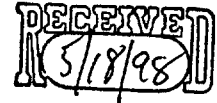
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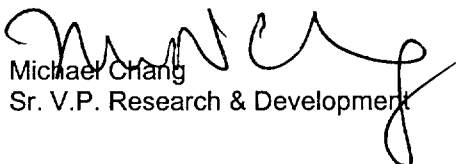
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Product identified as **Cranberry**, containing Cranberry fruit concentration (*Vaccinium macrocarpon*) with the following labeling statements:

1. Supports healthy urinary tract function.
2. Cranberry has been traditionally used as an aid to urinary tract health.
3. Cranberry may also lower urinary pH (and acidify the urine), which discourages the growth of bacteria.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

see docket 97S-0163 also

59146



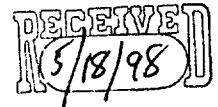
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Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **Goldenseal**, containing Goldenseal root extract (*Hydrastis canadensis*), with the following labeling statements:

1. Promotes healthy microbial environment.
2. Goldenseal promotes a healthy microbial environment in the body through the actions of its bioactive alkaloids (mostly hydrastine and berberine), which may block the adherence of microorganisms to host cells.
3. Goldenseal is often used to complement the proposed actions of Echinacea during the cold and wet weather seasons.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development

see also docket 97S-0163

59146